510(k) Summary
[As Required by 21 CFR 807.92]

MAY 27 2009

Submitter and Contact Information:

Submitter	Contact Person
Beckman Coulter, Inc. Clinical Systems Business Center 200 S. Kraemer Boulevard Brea, CA 92821	Mary Beth Tang Staff Regulatory Affairs Specialist Phone: 714-961-3777 Fax: 714-961-4234

Date Prepared

March 3, 2009

Device Name(s):

Trade Name:

Power Processor Sample Processing System
Generic Connection Module

Common Name:

Laboratory Automation System

Classification Names:

Discrete photometric chemistry analyzer for clinical use [862.2160]

Legally Marketed (Predicate) Devices:

Predicate Device	510(k) Number
Siemens (Dade Behring) StreamLAB® Analytical WorkCell/Sample Transfer Module	K043546
Beckman Coulter UniCel® DxI 800 Access® Immunoassay System	K023764
Beckman Coulter Access® Ferritin Assay	K926221
Beckman Coulter Access® Folate Assay	K060774
Beckman Coulter Access® HYPERsensitive hTSH Assay	K042281
Beckman Coulter Access® Vitamin B_{12} Assay	K955436

Intended Use

The basic Power Processor is an automated sample handling system which processes sample tubes from the pre-centrifugation, pre-sorting step to presentation of centrifuged and decapped samples into Generic or Personality Racks for specific instruments. The Power Processor can be configured with optional software and hardware to allow processing of sample tubes on Generic Connection Instruments. The Power Processor performs all pre-analytical sample tube preparation, and then sorts the sample tubes directly to Generic Connection Modules where the samples are pipetted by the Generic Connection instrument for testing. After the samples are pipetted, the tubes can route to other instruments for additional testing or to Outlet Racks.

The UniCel DxI 800 Access Immunoassay System with laboratory automation connection is a microcomputer-controlled, random and continuous access analyzer that includes an external computer. This computer stores the system user interface (UI) software and allows the operator to interface with and direct the instrument software. The UniCel DxI

800 System uses enzyme immunoassays (utilizing paramagnetic particle solid phase and chemiluminescent detection) for determination of various analytes, such as Vitamin B12, Ferritin, Folate and hTSH along with other various enzyme immunoassays assays that may be adaptable to the analyzer depending on the reagent used to induce the enzyme immunoassay reaction. The UniCel DxI 800 System is an in vitro diagnostic device for use in the clinical laboratory.

The Access Ferritin assay is a paramagnetic particle, chemiluminescent assay for the quantitative determination of ferritin levels in human serum and plasma (heparin) using the Access Immunoassay Systems. Measurements of ferritin aid in the diagnosis of diseases affecting iron metabolism.

The Access Folate assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of folic acid levels in human serum, plasma (heparin) and red blood cells using the Access Immunoassay Systems. Folic acid measurements are used in the diagnosis and treatment of megaloblastic anemia.

The Access HYPERsensitive hTSH assay is a paramagnetic particle, chemiluminescent assay for the quantitative determination of human thyroid-stimulating hormone (thyrotropin, hTSH) levels in human serum using the Access Immunoassay Systems. Measurements of thyroid stimulating hormone produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders.

The Access Vitamin B12 assay is a paramagnetic particle, chemiluminescent assay for the quantitative determination of vitamin B_{12} in human serum and plasma (heparin) using Access Immunoassay Systems. Measurements obtained by this device are used in the diagnosis and treatment of anemias of gastrointestinal malabsorption.

Device Description

The Power Processor is a scalable laboratory automation system (LAS) designed to streamline pre-analytical processes in the clinical laboratory. A basic Power Processor System is comprised of a Line Control Computer, Preplink™ Computer, Inlet Module, Hematology Module, Centrifugation Module, Decapper Module, and Outlet Module. In the basic configuration, patient sample tubes are loaded onto the Power Processor system to be sorted to a Hematology Module, or to be centrifuged, decapped, and sorted to Personality Racks for further processing on other instruments. Additional modules may be added for aliquot capability, sample capping, and refrigerated storage.

The Power Processor is an open architecture system that can connect to a variety of clinical analyzers. Connection modules are extensions of the Power Processor track system that link with an analyzer's existing LAS interface. Connection modules support one of two types of sample transfer methods: onboard or outboard sampling. Onboard sampling physically transfers the sample tube/rack from the automation track to the analyzer's sample load and identification area. With outboard sampling, the connection unit performs the sample bar code read function, presents the sample ID to the connected analyzer, and then signals for direct sampling of the open tube by the connected instrument at an aspiration point on the automation track. The Power Processor Generic Connection Module is specifically designed to support the outboard sampling method based on point-in-space pipetting technology aligned with the CSLI guidelines. This method is used to establish connection with Beckman Coulter's UniCel DxI 800 Immunoassay System. Power Processor software version 3.5 establishes a dynamic or "smart" connection with UniCel DxI 800 System to enable sample routing based on reagent and calibration status.

Substantial Equivalence Comparison

The Power Processor with Generic Connection (GC) Module is substantially equivalent in Intended Use and design characteristics to the primary predicate device. The secondary predicate serves as a representative analyzer connection for the outboard sampling method; in this configuration, the UniCel DxI 800 with Power Processor System and GC Module demonstrates substantial equivalence to the predicate UniCel DxI 800 Immunoassay System through an evaluation of assay performance.

Summary of Performance Data

Performance data from validation testing (system, software) supports equivalency. In addition, methods comparison studies were conducted with a representative assay menu to evaluate a representative connected system using on-line sample preparation against an unconnected analyzer using off-line centrifugation. These studies demonstrated good correlation between the Power Processor with GC module and UniCel DxI 800 connection and the stand-alone UniCel DxI 800 System.

Conclusion

The information provided in this submission supports a substantial equivalence determination, and therefore 510(k) premarket notification clearance of the Power Processor Sample Processing System with Generic Connection Module.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 27 2009

Beckman Coulter, Inc
c/o Mary B. Tang
Staff Regulatory Affairs Specialist
200 South Kraemer Blvd.
Brea, CA 92821

Re: k090588
Trade/Device Name: Power Processor Sample Processing System with Generic Connection Module, Model: 4210
Regulation Number: 21CFR Sec.-862.1810
Regulation Name: Vitamin B12 test system.
Regulatory Class: Class II
Product Code: CDD, DBF, CGN, JLW, JJE
Dated: March 3, 2009
Received: March 4, 2009

Dear Ms. Tang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

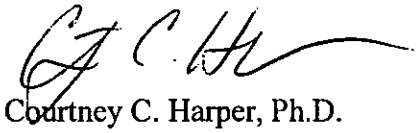
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): **K090588**

Device Name: **Power Processor Sample Processing System with Generic Connection Module and Access Immunoassay System Reagents**

Indication For Use:
The basic Power Processor is an automated sample handling system which processes sample tubes from the pre-centrifugation, pre-sorting step to presentation of centrifuged and decapped samples into Generic or Personality Racks for specific instruments. The Power Processor can be configured with optional software and hardware to allow processing of sample tubes on Generic Connection Instruments. The Power Processor performs all pre-analytical sample tube preparation, and then sorts the sample tubes directly to Generic Connection Modules where the samples are pipetted by the Generic Connection instrument for testing. After the samples are pipetted, the tubes can route to other instruments for additional testing or to Outlet Racks.

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Prescription Use __X__ (21 CFR Part 801 Subpart D)	And/Or	Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K090588

Indication for Use
(continued)

510(k) Number (if known): **K090588**

Device Name: **Power Processor Sample Processing System with Generic Connection Module and Access Immunoassay System Reagents**

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Prescription Use __X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K090588